K111648
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Submission Date:	06 June 2011
Submitter:	Bracco Diagnostics, Inc. 532 Broadhollow Road, Suite 126 Melville, NY 11747 USA
Submitter and Official Contact:	Ms. Tracey Alexander Director Regulatory Affairs +1 (609) 524-2865 +1 (631)-847-3904 (fax) tracey.alexander@diag.bracco.com
Trade Name:	Bracco Diagnostics, Inc. CO_2MPACT ENDOSCOPIC INSUFFLATOR™
Common Name:	CO_2 Insufflator
Classification Name:	Endoscope and accessories
Classification Regulation:	21 CFR §876.1500
Product Code:	FCX

Substantially Equivalent Devices:	*New BDI Model*	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	Bracco Diagnostics, Inc. CO_2MPACT ENDOSCOPIC INSUFFLATOR™	K053008	E-Z-EM, Inc. (now BDI) / CO_2Efficient Endoscopic Insufflator
		K081173	Olympus Medical Systems, Corp. / UCR Endoscopic CO2 Regulation Unit

Device Description:

The Bracco Diagnostics, Inc. (BDI), CO_2MPACT ENDOSCOPIC INSUFFLATOR™ (CO_2MPACT) is designed to use CO_2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope. The BDI CO_2MPACT regulates CO_2 flow rate and pressure during the insufflation process.

The BDI CO_2MPACT allows the physician to modulate and control the CO_2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Consistent with the predicate devices, the BDI CO_2MPACT is used to administer CO_2 to the patient for distention purposes. For this application, the actual displacement of CO_2 to the patient through the endoscope is controlled by the clinician modulating an "air-water" valve on the endoscope. The BDI CO_2MPACT only provides source pressure and flow to the endoscope in a similar manner to the predicates BDI CO_2Efficient Endoscopic Insufflator (K053008) and Olympus UCR Endoscopic CO_2 Regulation Unit (K081173), or the internal air pump included within the endoscope light source.

Intended Use:

The Bracco Diagnostics, Inc. (BDI) CO_2MPACT ENDOSCOPIC INSUFFLATOR™ is designed to use CO_2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The BDI CO_2MPACT ENDOSCOPIC INSUFFLATOR™ allows the physician to modulate and control the CO_2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Technology Comparison:

The BDI CO_2MPACT employs the same technological characteristics as the predicate devices.

Summary of Performance Testing:

Performance Testing

The BDI CO_2MPACT was tested for performance in accordance with internal requirements.

Test results indicated that the BDI CO_2MPACT complies with its predetermined specification and with the applicable Standards.

Biocompatibility Verification

Patient contact materials within the BDI CO_2MPACT and the tubing set was verified for performance in accordance with:

- *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*

Verification results indicated that the materials comply with predetermined specifications.

Software Testing

Software device modifications made to the BDI CO_2MPACT were designed and developed according to a robust software development process, and were rigorously verified and validated.

Software information is provided in accordance with:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05;*
- *FDA guidance: Off-the-shelf software use in medical devices, 09 Sep 99;*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02; and*
- *IEC 60601-1-4: 2000, Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems.*

Test results indicate that the BDI CO_2MPACT complies with its predetermined specification.

Special 510(k) Premarket Notification
Bracco Diagnostics, Inc.
CO_2MPACT ENDOSCOPIC INSUFFLATOR™
510(k) Summary

Electrical Safety Testing

The BDI CO_2MPACT was tested for patient safety in accordance with:

- *IEC 60601-1: 1988, Am1: 1991, Am2: 1995, Medical Electrical Equipment, Part 1: General Requirements for Safety; and*
- *UL 60601-1: 2006, Medical Electrical Equipment, Part 1: Particular Requirements for Safety.*

Test results indicated that the BDI CO_2MPACT complies with applicable Standards.

Electromagnetic Compatibility Testing

The BDI CO_2MPACT was tested for EMC in accordance with:

- *IEC 60601-1-2: 2007, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests*

Test results indicated that the BDI CO_2MPACT complies with applicable Standards.

Performance Testing – Bench

The BDI CO_2MPACT was tested for performance in accordance with internal requirements.

Test results indicated that the BDI CO2MPACT complies with applicable Standards.

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the BDI CO_2MPACT. The results of these activities demonstrate that the BDI CO_2MPACT is safe and effective when used in accordance with its intended use and labeling.

Therefore, the BDI CO_2MPACT is considered substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Tracey Alexander
Director Regulatory Affairs
Bracco Diagnostics, Inc.
532 Broadhollow Road, Suite 126
MELVILLE NY 11747

NOV - 3 2011

Re: K111648
Trade/Device Name: Bracco Diagnostics, Inc. CO_2MPACT ENDOSCOPIC INSUFFLATOR™
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCX
Dated: October 14, 2011
Received: October 20, 2011

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

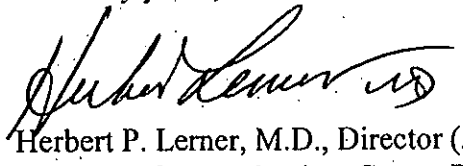
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111648

Device Name: Bracco Diagnostics, Inc. CO_2MPACT ENDOSCOPIC INSUFFLATOR™

Indications for Use:

The Bracco Diagnostics, Inc. (BDI) CO_2MPACT ENDOSCOPIC INSUFFLATOR™ is designed to use CO_2 as a distention media in the gastrointestinal tract when used in conjunction with a gastrointestinal endoscope.

The BDI CO_2MPACT ENDOSCOPIC INSUFFLATOR™ allows the physician to modulate and control the CO_2 to the patient in an identical manner to that being done currently with room air which is supplied by an air pump in the light source of the endoscopic equipment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111648